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APPLICATION NO 09/574,519 05/18/00 **HENDERSON** E 454357-4 **EXAMINER** 025934 HM12/1005 DORSEY & WHITNEY LLP FREDMAN.I 801 GRAND, SUITE 3900 PAPER NUMBER ART UNIT DES MOINES IA 50309 1655 DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

10/05/01 -



Office Action Summary

Application No.

09/574,519

Applit at(s)

Henderson et al

Examiner

Jeffrey Fredman

Art Unit **1655**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). 1) Responsive to communication(s) filed on Aug 16, 2001 2b) This action is non-final. 2a) This action is **FINAL**. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213. Disposition of Claims is/are pending in the application. 4) X Claim(s) 56-63 and 65-75 4a) Of the above, claim(s) ______ is/are withdrawn from consideration. 5) U Claim(s) 6) X Claim(s) <u>56-63 and 65-75</u> is/are rejected. is/are objected to. 7) Claim(s) are subject to restriction and/or election requirement. 8) Claims Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are objected to by the Examiner. 11) The proposed drawing correction filed on ______ is: a) approved b) disapproved. 12) The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. § 119 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d). a) All b) Some* c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). *See the attached detailed Office action for a list of the certified copies not received. 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). Attachment(s) 15) X Notice of References Cited (PTO-892) 18) Interview Summary (PTO-413) Paper No(s). 16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) Notice of Informal Patent Application (PTO-152) 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 20) Other:

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DETAILED ACTION

Continued Prosecution Application

1. The request filed on August 16, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/574,519 is acceptable and a CPA has been established. An action on the CPA follows.

Claim Rejections - 35 USC § 112

2. Claims 56-63 and 67-75 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." With regard to the new range restrictions in the claims, MPEP 2163.05 notes "With respect to changing numerical range limitations, the analysis must take into account which ranges one skilled in the art would consider inherently supported by the discussion in the original disclosure."

Here, the new limitations of "at least two biologically or chemically based molecules" where the change is the incorporation of the number "two" is not found to have basis in the specification. The cited portions of the specification only refer to "as little as one molecule of

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deposition material". This does not provide written descriptive support for the number two. This limitation is not found to be inherent in any disclosure of the specification.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- 4. Claims 56-63, 65, 67, 68 and 75 are rejected under 35 U.S.C. 102(a) as being anticipated by Dontha et al (J. Pharm. Biomed. Analysis (February 1999) 19:83-91).

Dontha teaches a molecular array for characterizing molecular interaction events comprising a) a surface (page 85, columns 1 and 2) and b) at least one molecular deposition domain deposited on said surface wherein the spatial address of the domain is less than one micron in area. Dontha expressly states "Sub-micron sized domains of a carbon surface are derivatized with antibodies using biotin/avidin technology (abstract)" (also see page 85, columns 1 and 2 and abstract). In figure 2, Dontha shows deposition domains which comprise spots, irregular shapes, some shapes which appear more linear and deposition of products at known locations. Dontha teaches that 10 microliters of photobiotin is used on a surface of 1 square mm diameter at a concentration of 10 mg/ml (page 85, column 1), and since photobiotin has a MW of 593.7, the solution of 10 microliters contains approximately 1 x 10¹⁷ molecules of photobiotin. This number, divided by the number of square microns per square mm which is 1.000.000.

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demonstrates that there are approximately 1 x 10¹¹ molecules of photobiotin spread over each micron, which is more than two molecules per deposition domain. This also meets the high density limitation and the array is inherently modified by a carboxyl group upon addition of the photobiotin. Dontha further teaches the express deposition of a protein and antibody onto the array which proteins inherently have the property of being either hydrophobic or hydrophilic (see figure 1, page 86).

Claim Rejections - 35 USC § 103

- 5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

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6. Claims 56-63 and 65-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dontha in view of Eggers et al (U.S. Patent 5,532,128) and further in view of Brenner (U.S. Patent 5,604,097).

Dontha teaches the limitations of claims 56-63, 65, 67, 68 and 75 as discussed above.

Dontha expressly indicates the method is of use for biomolecules (page 84, column 2). Dontha does not teach the particular equivalents, DNA, RNA, silanes or alkanethiolates.

Eggers teaches the placement of DNA, RNA, oligonucleotides thereof, antibodies, antigens and silanes onto solid supports (column 7, line 60 to column 8, line 15).

Brenner teaches the placement of alkanethiolates onto solid supports (column 12, line 45).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the Dontha array with the use of other molecules as taught by Eggers and Brenner since Dontha expressly motivates the use of other biomolecules (page 84, column 2) and since Eggers demonstrates the eqivalence of these items, stating "Different probes can be attached to the test sites 14 according to the type of target desired, including the use of oligonucleotides, single or double stranded DNA or RNA, antibodies or antigen-antibody complexes, tumor cells and other test probes known to those of skill in the art (column 7, lines 61-66)". As MPEP 2144.06 notes "Substituting equivalents known for the same purpose. In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. An express suggestion to

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substitute one equivalent component or process for another is not necessary to render such substitution obvious. In re Fout, 675 F.2d 297, 213 USPQ 532 (CCPA 1982)." Here, Eggers and Brenner demonstrate the equivalency in the prior art.

Response to Arguments

7. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman, Ph.D. whose telephone number is (703) 308-6568.

The examiner is normally in the office between the hours of 6:30 a.m. and 4:00 p.m. and telephone calls either in the early morning or the afternoon are most likely to find the examiner in the office.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 are either (703) 305-3014 or (703) 308-4242. Please note that the faxing of such papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Jeffrey Fredman
Primary Patent Examiner
Art Unit 1655

September 26, 2001